General

Guideline Title

Congress of Neurological Surgeons systematic review and evidence-based guideline on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly.

Bibliographic Source(s)

Tamber MS, Nikas D, Beier A, Baird LC, Bauer DF, Durham S, Klimo P Jr, Lin AY, Mazzola C, McClung-Smith C, Mitchell L, Tyagi R, Flannery AM. Congress of Neurological Surgeons systematic review and evidence-based guideline on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly. Neurosurgery. 2016 Nov;79(5):E632-3. PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the levels of recommendations (I-III) are provided at the end of the "Major Recommendations" field.

Recommendations

1. Helmet therapy is recommended for infants with persistent moderate to severe plagiocephaly after a course of conservative treatment (repositioning and/or physical therapy).
   Strength of Recommendation: Level II—uncertain clinical certainty
2. Helmet therapy is recommended for infants with moderate to severe plagiocephaly presenting at an advanced age.
   Strength of Recommendation: Level II—uncertain clinical certainty

Definitions

Classification of Evidence and Levels of Recommendation on Therapeutic Effectiveness

Class I Evidence Level I (or A) Recommendation	Evidence from one or more well-designed, randomized controlled clinical trials, including overviews of such trials.
Class II	Evidence from one or more well-designed comparative clinical studies, such as non-randomized cohort studies, case-

Evidence Level II (or B) Recommendation	control studies, and other comparable studies, including less well-designed randomized controlled trials.
Class III Evidence Level III (or C) Recommendation	Evidence from case series, comparative studies with historical controls, case reports, and expert opinion, as well as significantly flawed randomized controlled trials.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Positional plagiocephaly

Guideline Category

Assessment of Therapeutic Effectiveness

Management

Treatment

Clinical Specialty

Neurology

Pediatrics

Physical Medicine and Rehabilitation

Intended Users

Physical Therapists

Physicians

Guideline Objective(s)

To address the clinical question "Does helmet therapy provide effective treatment for positional plagiocephaly?" and to make treatment recommendations based on the available evidence

Target Population

Infants with positional plagiocephaly

Interventions and Practices Considered

1. Helmet therapy
2. Conservative treatment (repositioning or physical therapy)

Major Outcomes Considered

Improvement in cranial asymmetry as assessed by change in 2- or 3-dimensional anthropometric measurements or subjective physician or parent evaluation

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

General Search Strategy

Literature Search

The task force worked with medical librarians to determine appropriate search terms and to create search strategies for each guideline chapter. The National Library of Medicine and the Cochrane Library were searched for literature published between 1966 and October 2014. Task force members used the article inclusion/exclusion criteria described below to screen abstracts and provide a list of relevant articles for full-text review. Task force members were blinded to the selection of abstracts provided by other task force members. Congress of Neurological Surgeons (CNS) staff compiled lists of manuscripts for full-text review and approval by all of the task force members, and these full-text articles were reviewed by all task force members. In addition, task force members also screened the bibliographies of relevant systematic reviews for potentially relevant articles.

Article Inclusion Criteria

Included articles must have met certain criteria, as detailed below. To reduce bias, these criteria were specified before conducting the literature searches. To be included in the review, an article had to meet the following criteria:

- Studies had to investigate pediatric (<18 years of age) patients with non-synostotic plagiocephaly or brachycephaly.
- Studies with mixed patient populations and that combined the results of these patient groups must have enrolled ≥80% of pediatric patients with plagiocephaly or brachycephaly.
- The study was a full article report of a clinical study.
- Studies had to have appeared in a peer-reviewed publication or a registry report.
- Studies had to enroll at least 10 patients (5 per treatment arm) for each distinct outcome measured. If it was a comparative study, a minimum enrollment of 5 patients per treatment arm for each outcome was necessary.
- The study involved humans.
- The study was published in or after 1966.
- The study presented results quantitatively.
- The study did not involve "in vitro," "biomechanical," or results performed on cadavers.
- The study was published in English.

Systematic reviews, meta-analyses, or guidelines developed by others were not considered as evidence to support this guideline. The task force screened the bibliographies of these publications to ensure the accuracy and comprehensiveness of the literature search results used for this guideline.

Specific Search Strategy for This Guideline

Literature Search

The task force collaborated with medical librarians to search for articles published in the US National Library of Medicine (PubMed/MEDLINE) database and the Cochrane Library for the period January 1966 through October 2014, using the MeSH subject headings and PubMed search strategies provided in Appendix A of the full version of the guideline (see the "Availability of Companion Documents" field). Manual searches of bibliographies were also conducted.

Article Inclusion/Exclusion Criteria

The task force reviewed the titles and abstracts to identify studies that would address the effectiveness of cranial remolding orthosis (helmet) therapy compared to other treatments for positional plagiocephaly (including no treatment). Studies in which there was no comparison group (uncontrolled) were excluded, as without a control or reference group, it is impossible to judge whether or not an intervention is effective. Studies that employed survey methodology were also excluded. Articles that met these criteria were independently reviewed by 3 of the authors, and appropriate studies were selected for inclusion into the evidence tables for this recommendation.

Search Results

The Medline plagiocephaly search (search #1) returned 88 abstracts, while the Medline brachycephaly (search #2) and Cochrane plagiocephaly/brachycephaly (search #3) searches returned 22 and 19 abstracts, respectively (see Figure 1 in the full version of the guideline [see the "Availability of Companion Documents" field]). After removal of duplicate results, 102 abstracts were screened in total. After review of the abstracts, 41 full-text articles were reviewed (38 articles were selected after reviewing the abstracts, and an additional 3 articles were obtained after examination of the bibliographies of the 38 initially selected articles). Of the 41 full-text articles reviewed, 26 were rejected for the following reasons: no comparison group, use of a non-helmet orthosis, comparison group did not have plagiocephaly, and study used survey methodology.

Number of Source Documents

15 articles satisfied the criteria for inclusion into the evidence tables. See Figure 1 in the full version of the guideline (see the "Availability of Companion Documents" field).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Classification of Evidence and Levels of Recommendation on Therapeutic Effectiveness

Class I Evidence Level I (or A) Recommendation	Evidence from one or more well-designed, randomized controlled clinical trials, including overviews of such trials.
Class II Evidence Level II (or B) Recommendation	Evidence from one or more well-designed comparative clinical studies, such as non-randomized cohort studies, case-control studies, and other comparable studies, including less well-designed randomized controlled trials.
Class III Evidence Level III (or C) Recommendation	Evidence from case series, comparative studies with historical controls, case reports, and expert opinion, as well as significantly flawed randomized controlled trials.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidentiary tables were constructed that summarized pertinent study results.

Rating Quality of Evidence

The quality of evidence was rated using an evidence hierarchy developed by the Joint Guidelines Committee for each of the 4 different study types (i.e., therapeutic, diagnostic, prognostic, and clinical assessment).

Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

The development of these guidelines was initiated by the Congress of Neurological Surgeons (CNS) and the Section on Pediatric Neurosurgery in response to members' concerns about the variation in the diagnosis and treatment paradigms being utilized. A multidisciplinary team comprised of physician volunteers (clinical experts), a clinical guidelines expert, and medical librarians was convened to conduct a systematic search of the literature and prepare clinical guidelines on the topic of pediatric plagiocephaly. After initial discussions, the members of the Plagiocephaly Guideline Task Force (hereinafter referred to as "the task force") decided, a priori, that the 4 major sub-topics would include: imaging modalities in the diagnosis of plagiocephaly, repositioning, physical therapy, and molding orthoses (helmet therapy).

Strength of Recommendations Rating Scheme

The task force used the methodologies endorsed by the Joint Guidelines Committee (JGC) to assign a strength of recommendation for each recommendation included in this guideline. Linking evidence to recommendations, through the utilization of evidentiary tables, has been endorsed by the American Medical Association (AMA), the CNS, and the American Association of Neurological Surgeons (AANS). This process validates and supports the relationship between the strength of evidence and the strength of recommendations.

Demonstrating the highest degree of clinical certainty, Class I evidence is used to support recommendations of the strongest type, defined as Level I recommendations. Level II recommendations reflect a moderate degree of clinical certainty and are supported by Class II evidence or strong consensus of Class III evidence. Level III recommendations denote clinical uncertainty supported by inconclusive or conflicting evidence or expert opinion.

Voting on the Recommendations

The task force used voting among its members to approve the final recommendations, language, and strength of recommendations. The voting was used to ensure that the language of each recommendation accurately reflected the evidence and the strength of the evidence. All the recommendations in this review were approved following the first round of voting, and no further discussion was needed to finalize the recommendations. The voting technique is referred to as the nominal group technique. During the course of editing and finalization of the document, changes were made to allow recommendations to conform to the rules of evidence and language as described above. When this occurred, the changes were reviewed and approved by the group.

Guideline Panel Consensus and Approval Process

Topic teams were created from the task force based on expertise of the task force members with respect to each topic addressed within the review. Each group took part in literature selection, review of the literature, creation of the evidence tables, creation of the guideline, editing, and final review. The final draft of the guideline was then circulated to the entire task force for feedback, discussion, and ultimately approval.

Rating Scheme for the Strength of the Recommendations

See the "Rating Scheme for the Strength of the Evidence" field.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Following task force approval, drafts of the completed guidelines were presented to the Joint Guidelines Committee (JGC) for peer review and, ultimately, recommendation of endorsement by the Congress of Neurological Surgeons (CNS) and the American Association of Neurological Surgeons (AANS). The reviewers for the JGC were vetted by the editorial staff of the journal *Neurosurgery*. During the review process, the peer reviewers were blinded to the identities of the task force members. As part of the evaluation process, reviewers could provide input on the content and the methodologies used to create the systematic review.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for the recommendation (see the "Major Recommendations" field). There was 1 prospective randomized controlled trial (Class II), 5 prospective comparative studies (Class II), and 9 retrospective comparative studies (Class II).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

There is a fairly substantive body of nonrandomized evidence that demonstrates more significant and faster improvement of cranial shape in infants with positional plagiocephaly treated with a helmet in comparison with conservative therapy, especially if the asymmetry is severe, provided that helmet therapy is applied during the appropriate period of infancy.

Potential Harms

- Frequent regular assessments are required to assess for cranial growth and the presence of any adverse effects, as well as to make any necessary adjustments to the device to allow for continual growth and change in shape of the calvarium.
- Evidence in favor of helmet use must be tempered by the lack of data regarding the extent of natural improvement of positional plagiocephaly, the long-term effects of helmet therapy (and of "untreated" plagiocephaly), and the costs associated with helmet therapy.

Qualifying Statements

Qualifying Statements

Disclaimer of Liability

This clinical systematic review and evidence-based guideline was developed by a physician volunteer task force as an educational tool that reflects the current state of knowledge at the time of completion. The presentations are designed to provide an accurate review of the subject matter covered. This guideline is disseminated with the understanding that the recommendations by the authors and consultants who have collaborated in its development are not meant to replace the individualized care and treatment advice from a patient's physician(s). If medical advice or assistance

is required, the services of a physician should be sought. The recommendations contained in this guideline may not be suitable for use in all circumstances. The choice to implement any particular recommendation contained in this guideline must be made by a managing physician in light of the situation in each particular patient and on the basis of existing resources.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Tamber MS, Nikas D, Beier A, Baird LC, Bauer DF, Durham S, Klimo P Jr, Lin AY, Mazzola C, McClung-Smith C, Mitchell L, Tyagi R, Flannery AM. Congress of Neurological Surgeons systematic review and evidence-based guideline on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly. Neurosurgery. 2016 Nov;79(5):E632-3. PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Nov

Guideline Developer(s)

Congress of Neurological Surgeons - Professional Association

Source(s) of Funding

These evidence-based clinical practice guidelines were funded exclusively by the Congress of Neurological Surgeons and the Section on Pediatric Neurosurgery of the Congress of Neurological Surgeons and the American Association of Neurological Surgeons, which received no funding from outside commercial sources to support the development of this document.

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

Guideline Committee

Plagiocephaly Guideline Task Force

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Potential Conflicts of Interest

All guideline task force members were required to disclose all potential conflicts of interest (COIs) prior to beginning work on the guideline, using the COI disclosure form of the Joint Guidelines Committee of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) (hereinafter referred to as the Joint Guidelines Committee). The CNS Guidelines Committee and the task force chair reviewed any disclosures and either approved or disapproved the nomination and participation on the task force. The CNS Guidelines Committee and the task force chair may approve nominations of task force members with possible conflicts and restrict the writing, reviewing, and/or voting privileges of that person to topics that are unrelated to the possible COIs.

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

Guideline Endorser(s)

American Academy of Pediatrics - Medical Specialty Society

American Association of Neurological Surgeons - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Neurosurgery Web site . Also available in ePub from the Neurosurgery Web site .

Availability of Companion Documents

The following are available:

- Congress of Neurological Surgeons systematic review and evidence-based guideline on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly. Full guideline. 2016 Nov. 34 p. Available from the Congress of Neurological Surgeons (CNS) Web site .
- Flannery AM, Mitchell L, Mazzola C, Klimo P Jr., Baird LC, Tamber MS, Bauer DF, Beier A, Durham S, Lin AY, McClung-Smith C, Nikas D, Tyagi R. Congress of Neurological Surgeons systematic review and evidence-based guideline for the management of patients with positional plagiocephaly: introduction and methods. 2016 Nov. 12 p. Available from the CNS Web site .
- Flannery AM, Tamber MS, Mazzola C, Klimo P Jr, Baird LC, Tyagi R, Bauer DF, Beier A, Durham S, Lin AY, McClung-Smith C, Mitchell L, Nikas, D. Congress of Neurological Surgeons systematic review and evidence-based guidelines for the management of patients with positional plagiocephaly: executive summary. Neurosurgery. 2016 Nov;79(5):623-4. Available from the Neurosurgery Web site .
- Congress of Neurological Surgeons (CNS). Guideline development methodology: endorsed by the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Guideline Committee. Schaumburg (IL): Congress of Neurological Surgeons (CNS); 2012 Feb. 12 p. Available from the CNS Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on February 3, 2017. The information was verified by the guideline developer on February 23, 2017.

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